

IN THE CLAIMS:

(Sub 6)

1. A method of ablating tissue within a body of a patient comprising:
providing an elongated flexible tubular member having at least one lumen and a distal end portion;
5 providing an ablative device which is configured to be longitudinally received within said at least one lumen of said flexible tubular member, said ablative device having an energy delivery portion which is coupled to a source of ablative energy;
introducing said flexible tubular member into the patient's body and
10 positioning the distal end portion of the tubular member adjacent to or in contact with a tissue region to be ablated;
transluminally positioning the ablative device through the at least one lumen of the flexible tubular member until the energy delivery portion is located at least partially within said distal end portion; and
15 delivering ablative energy to said energy delivery portion to ablate said tissue region.
2. The method of claim 1 wherein
the distal end portion is pre-shaped.
20
3. The method of claim 1 wherein
the distal end portion is malleable.
25
4. The method of claim 1 wherein
said introducing said flexible tubular member into the patient's body comprises
introducing the flexible tubular member through an opening in the body of the patient.
5. The method of claim 4 wherein
said opening in the body is located in the chest of the patient.
30
6. The method of claim 5 wherein

100-221-224-00

1 said flexible tubular member is inserted through a partial or median sternotomy opening in the chest.

2 7. The method of claim 5 wherein
3 said flexible tubular member is inserted through a thorascopic opening
4 in the chest.

5 8. The method of claim 5 wherein
6 said flexible tubular member is inserted through a percutaneous portal
7 access opening in the chest.

8 9. The method of claim 1 wherein
9 said tissue region to be ablated is a tissue region located within or on an
10 organ or vessel selected from the group consisting of a heart, a stomach, a liver,
11 a pancreas, a kidney, an esophagus, an intestine, a uterus, a spleen, a prostate,
12 or a brain.

13 10. The method of claim 4 further comprising
14 positioning the distal end portion of the flexible tubular member
15 adjacent to or in contact with an epicardium of the heart of the patient.

16 11. The method of claim 10 wherein
17 the heart remains beating during said positioning of the distal end
18 portion.

19 12. The method of claim 10 further comprising:
20 positioning the distal end portion of the flexible tubular member
21 adjacent to or in contact with at least a portion of the transverse sinus
22 preparatory to treating atrial fibrillation.

23 13. The method of claim 10 wherein

0005227-227460

14. The method of claim 10 wherein
5 said distal end portion is positioned adjacent to or in contact with a posterior wall of a left atrium proximate to a junction between a pulmonary vein and the left atrium of the heart.

15. The method of claim 10 wherein
10 said distal end portion is positioned substantially adjacent to a pulmonary vein on an epicardial surface of the heart.

16. The method of claim 15 further comprising
15 repeating said positioning the distal end portion and said delivering ablative energy two or more times to create a substantially annular ablation around one or more pulmonary veins of the heart of the patient.

17. The method of claim 4 further comprising
20 forming a penetration through a muscular wall of the heart into an interior chamber thereof and
 positioning the distal end portion of the flexible tubular member through the penetration.

18. The method of claim 17 further comprising
25 positioning the distal end portion of the elongated tubular member adjacent to or in contact with a tissue surface of an interior wall of an interior chamber of the heart.

19. The method of claim 18 further comprising

positioning the distal end portion of the elongated tubular member adjacent to or in contact with a tissue surface of an interior wall of a hollow organ.

5 20. The method of claim 18 wherein
 the interior chamber is selected from a right atrium or a left atrium.

10 21. The method of claim 20 wherein
 the distal end portion is pre-shaped to extend at an angle of from
 between about 0 and 90 degrees relative to a longitudinal axis of the tubular
 member.

15 22. The method of claim 20 wherein
 the distal end portion is annular shaped.

20 23. The method of claim 1 wherein said energy delivery portion is flexible.

25 24. The method of claim 1 wherein said energy delivery portion is
 unidirectional.

30 25. The method of claim 1 wherein
 said energy delivery portion comprises a microwave ablation element.

25 26. The method of claim 25 wherein
 said microwave ablation element is flexible.

27. The method of claim 25 wherein
 said microwave ablation element is directional

30 28. The method of claim 1 wherein

100-62021-22245-260

1 said energy delivery portion comprises a radiofrequency ablation element.

29. The method of claim 28 wherein
5 said radiofrequency ablation element is flexible.

30. The method of claim 28 wherein
said radiofrequency ablation element is directional.

10 31. The method of claim 1 wherein
said energy delivery portion comprises an ultrasound ablation element.

32. The method of claim 31 wherein
15 said ultrasound ablation element is flexible.

33. The method of claim 31 wherein
said ultrasound ablation element is directional.

34. The method of claim 1 wherein
20 said energy delivery portion comprises a laser ablation element.

35. The method of claim 34 wherein
said laser ablation element is flexible.

25 36. The method of claim 34 wherein
said laser ablation element is directional.

37. The method of claim 1 wherein
30 said energy delivery portion comprises a fluid delivery element.

38. The method of claim 37 wherein

said fluid delivery element is flexible.

39. The method of claim 37 wherein
said fluid delivery element is directional.
5

40. The method of claim 1 wherein
said energy delivery portion comprises a cryogenic ablation element.

41. The method of claim 40 wherein
10 said cryogenic ablation element is flexible.

42. The method of claim 40 wherein
said cryogenic ablation element is directional.

15 43. The method of claim 1 further comprising
repositioning the energy delivery portion of the ablative device within
the distal end portion of the flexible tubular member at least once to form a
plurality of strategically positioned lesions along said tissue region.

20 44. The method of claim 43 wherein
at least a portion of respective ones of said plurality of lesions overlap
one another to form a continuous lesion.

45. The method of claim 44 wherein
25 said plurality of lesions are formed in a substantially rectilinear pattern.

46. The method of claim 44 wherein
said plurality of lesions are formed in a substantially curvilinear pattern.

30 47. The method of claim 44 wherein
said plurality of lesions are formed in a substantially annular pattern.

00000000000000000000000000000000

48. The method of claim 1 further comprising
positioning the distal end portion of the flexible tubular member
adjacent to or in contact with a tissue region within an interior chamber of the
heart of a patient.

49. The method of claim 4 wherein
said energy delivery portion comprises a microwave ablation element.

10 50. The method of claim 49 wherein
said microwave ablation element is directional.

51. The method of claim 24 wherein
said flexible tubular member includes a key assembly to properly align
the energy delivery portion within the distal end portion of the flexible tubular
member such that the predetermined direction of the ablative energy aligns
with the tissue region to be ablated.

20 52. The method of claim 49 wherein
said microwave ablation element comprises a microwave antenna which
is located within an antenna assembly of the instrument for generating an
electromagnetic field sufficient to cause ablation of said tissue region, said
antenna assembly being adapted to direct the majority of the electromagnetic
field generally in a predetermined direction across the distal end portion of the
flexible tubular member.

25 53. The method of claim 52, wherein
said antenna is configured to generate said electromagnetic field
substantially radially from a longitudinal axis of the antenna, and said antenna
assembly includes an elongated shield extending partially around and generally
in the direction of the longitudinal axis of the antenna, said shield defining an

(1)

opening adapted to direct said majority of the electromagnetic field generally in said predetermined direction.

54. The method of claim 52 wherein
5 said flexible tubular member includes a key assembly to properly align the antenna assembly within the distal end portion of the flexible tubular member such that the predetermined direction of the electromagnetic field aligns with the tissue region to be ablated.

10 55. The method of claim 4 wherein
 said energy delivery portion comprises a laser ablation element.

15 56. The method of claim 55 wherein
 said laser ablation element is directional.

20 57. The method of claim 55 wherein
 said laser ablation element comprises a laser emitting element which is located within a laser emitting assembly of the instrument for generating an electromagnetic field sufficient to cause ablation of said tissue region, said laser emitting assembly being adapted to direct the majority of the electromagnetic field generally in a predetermined direction across the distal end portion of the flexible tubular member.

25 58. The method of claim 57, wherein
 said laser emitting element is configured to generate said electromagnetic field substantially radially from a longitudinal axis of the laser emitting element, and said laser emitting assembly includes an elongated reflector extending partially around and generally in the direction of the longitudinal axis of the laser emitting element, said shield defining an opening adapted to direct said majority of the electromagnetic field generally in said predetermined direction.

100-200-300-400-500-600

59. The method of claim 57 wherein
said flexible tubular member includes a key assembly to properly align the laser
emitting assembly within the distal end portion of the flexible tubular member
such that the predetermined direction of the electromagnetic field aligns with
the tissue region to be ablated.

60. The method of claim 4 wherein
said energy delivery portion comprises a ultrasound ablation element.

10 61. The method of claim 60 wherein
said ultrasound ablation element is directional.

62. The method of claim 60 wherein
15 said ultrasound ablation element comprises at least one ultrasound
transducer which is located within an ultrasound ablation assembly of the
instrument for generating an acoustic pressure wave sufficient to cause ablation
of said tissue region, said ultrasound ablation assembly being adapted to direct
the majority of the acoustic pressure wave generally in a predetermined
20 direction across the distal end portion of the flexible tubular member.

63. The method of claim 62, wherein
said ultrasound transducer is configured to generate said acoustic
pressure wave substantially radially from a longitudinal axis of the ultrasound
25 ablation element, and said ultrasound ablation assembly includes an good
echogenic material extending partially around and generally in the direction of
the longitudinal axis of the ultrasound transducer, said echogenic material
defining an opening adapted to direct said majority of the acoustic pressure
wave generally in said predetermined direction.

30 64. The method of claim 62 wherein

said flexible tubular member includes a key assembly to properly align the ultrasound ablation assembly within the distal end portion of the flexible tubular member such that the predetermined direction of the acoustic pressure wave aligns with the tissue region to be ablated.

5

65. The method of claim 4 wherein
said energy delivery portion comprises a cryoablation element.

66. The method of claim 65 wherein
10 said cryoablation element is directional.

67. The method of claim 65 wherein
said cryoablation element comprises a decompression chamber which is located within a cryoablation assembly of the instrument for generating a 15 thermal sink sufficient to cause ablation of said tissue region, said cryoablation assembly being adapted to direct the majority of the thermal conduction generally in a predetermined direction across the distal end portion of the flexible tubular member.

20 68. The method of claim 67, wherein
said decompression chamber is configured to generate said thermal sink substantially radially from a longitudinal axis of the cryoablation element, and said cryoablation assembly includes an elongated thermal isolating element extending partially around and generally in the direction of the longitudinal 25 axis of the cryoablation element, said thermal isolating element defining an opening adapted to direct said majority of the thermal conduction generally in said predetermined direction.

69. The method of claim 67 wherein
30 said flexible tubular member includes a key assembly to properly align the cryoablation assembly within the distal end portion of the flexible tubular

member such that the predetermined direction of the thermal conduction aligns with the tissue region to be ablated.

70. The method of claim 1 wherein

5 said flexible tubular member comprises one or more electrodes coupled to said distal end portion of the flexible tubular member, said method further comprising

sensing contact between the flexible tubular member and the tissue region to be ablated using said one or more electrodes.

10

71. The method of claim 1 wherein

said distal end portion of the flexible tubular member includes at least first and second sections, said first section having a loop configuration sized and dimensioned to substantially encircle an opening to a pulmonary vein, and 15 said second section extending from said first section and having a substantially longitudinal configuration..

72. The method of claim 71 wherein

20 said second section includes at least one electrode.

20

73. The method of claim 71 further comprising

introducing the distal end portion of the flexible tubular member into an atrium of the heart such that the first section substantially encircles the opening to the pulmonary vein and said second section extends a short distance into the 25 vein through the opening thereof.

74. The method of claim 73 further comprising

sensing electrical activity within the pulmonary vein with said at least one electrode.

30

75. The method of claim 73 further comprising

006247-2475260

assessing the electrical isolation of the pulmonary vein by using said at least one electrode to attempt to pace the heart from within the pulmonary vein.

76. The method of claim 73 further comprising
5 assessing the electrical isolation of the pulmonary vein by using said at least one electrode to attempt to monitor the electrical activation from the left atrium.

77. The method of claim 73 further comprising
10 introducing at least one contrast agent through said at least one lumen of the flexible tubular member into the pulmonary vein.

78. The method of claim 1 wherein
15 said distal end portion of the flexible tubular member includes at least one temperature sensor, said method further comprising measuring a temperature of the tissue region using said temperature sensor.

79. The method of claim 1 wherein
20 said ablative device includes at least one temperature sensor, said method further comprising measuring a temperature from within the flexible tubular member at one or more locations within the tubular member using the temperature sensor.

25 80. The method of claim 1 further comprising:
providing a guide sheath having a pre-shaped distal end portion;
providing an introducer sheath having a distal end;
introducing the introducer sheath into an interior chamber of the heart;
telescopically introducing the guide sheath through the introducer sheath
30 such that the pre-shaped distal end portion of the guide sheath extends a short distance beyond the distal end of the introducer sheath in a direction which is

REF ID: A6200

sufficient to direct the distal end portion of the flexible tubular member towards the tissue region to be ablated; and

telescopically introducing the flexible tubular member through the guide catheter to position the distal end portion adjacent to or in contact with the tissue region to be ablated.

5 81. The method of claim 80 wherein
 the interior chamber is selected from a right atrium or a left atrium.

10 82. The method of claim 80 wherein
 the interior chamber is selected from a right ventricle or a left ventricle.

15 83. The method of claim 80 wherein
 said introducer sheath is sized and dimensioned to extend into an interior chamber of the heart from a peripheral access vessel in the arm or leg of the patient.

20 84. The method of claim 80 wherein
 said introducer sheath is sized and dimensioned to extend into an interior chamber of the heart of the patient from a jugular vein of the patient.

25 85. The method of claim 80 wherein
 said introducer sheath is sized and dimensioned to extend into an interior chamber of the heart of the patient from a subclavian vein of the patient.

30 86. The method of claim 1 further comprising:
 providing a guide sheath having a pre-shaped distal end portion;
 introducing the guide sheath into an interior chamber of the heart such that the distal end portion extends in a direction which is sufficient to direct the distal end portion of the flexible tubular member towards the tissue region to be ablated; and

(b) (4)

telescopically introducing the flexible tubular member through the guide sheath to position the distal end portion adjacent to or in contact with the tissue region to be ablated.

5 87. The method of claim 86 wherein
 the interior chamber is selected from a right atrium or a left atrium.

88. The method of claim 86 wherein
 the interior chamber is selected from a right ventricle or a left ventricle.

10 89. The method of claim 86 wherein
 said guide catheter is sized and dimensioned to extend into an interior chamber of the heart from a peripheral access vessel in the arm or leg of the patient.

15 90. The method of claim 86 wherein
 said introducer sheath is sized and dimensioned to extend into an interior chamber of the heart of the patient from a jugular vein of the patient.

20 91. The method of claim 86 wherein
 said introducer sheath is sized and dimensioned to extend into an interior chamber of the heart of the patient from a subclavian vein of the patient.

25 92. The method of claim 1, wherein
 said tubular member includes a window portion in a portion of a side wall of the tubular member near the distal end portion of the tubular member, and
 said positioning the tubular member comprises positioning the window portion adjacent to or in contact with the tissue region to be ablated.

30 93. The method of claim 92, wherein

□□□□□

said transluminally positioning the ablative device through the tubular member comprises positioning at least a portion of the energy delivery portion of the ablative device proximate to said window portion.

5 94. The method of claim 93, wherein
 said window portion is formed of a material used to obtain a good
energy transfer between the ablative device and the tissue to ablate.

10 95. The method of claim 93, wherein
 said window portion is formed of a material with a low water absorption
coefficient.

15 96. The method of claim 94, wherein
 said ablative device comprises at least one ultrasonic ablation element.

20 97. The method of claim 93, wherein
 said window portion comprises a removed portion of the side wall of the
tubular member and wherein said ablative device comprises a ultrasonic
ablation element.

25 98. The method of claim 93, wherein
 said window portion is formed of a laser transparent material and said
ablative device comprises a laser emitting element.

30 99. The method of claim 93, wherein
 said window portion comprises a removed portion of the side wall of the
tubular member and wherein said ablative device comprises a laser ablation
element.

100. The method of claim 93, wherein

said window portion is formed of a electrically conductive material and said ablative device comprises a RF ablation element.

101. The method of claim 93, wherein

5 said window portion is formed of a dielectric material having a low loss-tangent at microwave frequencies and said ablative device comprises a microwave ablation element.

102. The method of claim 93, wherein

10 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a microwave ablation element.

103. The method of claim 93, wherein

15 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a microwave ablation element.

104. The method of claim 93, wherein

20 said window portion is formed of a good thermal conductor material and said ablative device comprises a cryoablation element.

105. The method of claim 93, wherein

25 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a cryoablation element.

106. A method of ablating tissue comprising:

30 positioning a pre-shaped distal end portion of a guide catheter proximate to a tissue region to be ablated of a body structure;

transluminally positioning an energy delivery portion of an ablative device through said guide catheter until said energy delivery portion is located within at least a portion of said distal end portion;

5 delivering sufficient energy to said energy delivery portion to ablate said tissue region through said distal end portion of the guide catheter.

107. A method of ablating tissue within an interior chamber of a patient's heart comprising:

10 providing a flexible tubular member having a distal end portion which is shaped to substantially conform the distal end portion to a tissue region within an atrial chamber of the patient's heart;

introducing the flexible tubular member into an atrial chamber of the heart and positioning the distal end portion adjacent to or in contact with the tissue region;

15 transluminally positioning an energy delivery portion of an ablative device through said flexible tubular member until said energy delivery portion is at least partially located within said distal end portion;

delivering ablative energy to said energy delivery portion to ablate said tissue region.

20 108. A system for ablating tissue within a body of a patient comprising:

an elongated flexible tubular member having at least one lumen and including a pre-shaped distal end portion which is shaped to be positioned adjacent to or in contact with a selected tissue region within the body of the patient; and

25 an ablative device which is configured to be slideably received longitudinally within said at least one lumen and having an energy delivery portion located near a distal end portion of said ablative device which is adapted to be coupled to an ablative energy source.

30 109. The system of claim 108 wherein

1
said energy delivery portion and ablative energy source are working together to produce the ablation of said selected tissue region.

5 110. The system of claim 108 wherein
said flexible tubular member includes at least one radio-opaque element.

10 111. The system of claim 110 wherein
said radio-opaque element can be used to assess the shape of the flexible tubular member during a fluoroscopic procedure.

112. The system of claim 108 wherein
said energy delivery portion includes at least one radio-opaque element.

15 113. The system of claim 112 wherein
said radio-opaque element is strategically located to identify the extremities of said energy delivery portion.

20 114. The system of claim 112 wherein
said radio-opaque element is strategically located to identify the ablation location.

25 115. The system of claim 116 further including
an introducer which is configured to longitudinally receive said flexible tubular member.

30 116. The system of claim 115 wherein
said introducer has a pre-shaped distal end portion which is configured to be manipulated to direct the flexible tubular member towards the selected tissue region to be ablated following insertion of the distal end portion of the introducer into an interior chamber of the heart.

RECEIVED
U.S. PATENT AND TRADEMARK OFFICE

117. The system of claim 108 wherein
said distal end portion of the flexible tubular member has a distal end
which is closed.

5 118. The system of claim 108 wherein said energy delivery portion is
flexible.

119. The system of claim 108 wherein said energy delivery portion is
unidirectional.

10 120. The system of claim 108 wherein
said energy delivery portion comprises a microwave ablation element.

15 121. The system of claim 120 wherein
said microwave ablation element is flexible.

122. The system of claim 120 wherein
said microwave ablation element is directional

20 123. The system of claim 108 wherein
said ablative device is a laser ablation element.

124. The system of claim 123 wherein
said laser ablation element is flexible.

25 125. The system of claim 123 wherein
said laser ablation element is directional.

126. The system of claim 108 wherein
30 said energy delivery portion comprises a radiofrequency ablation
element.

RECEIVED - 2016 SEP 26 PM

127. The system of claim 126 wherein
said radiofrequency ablation element is flexible.

5 128. The system of claim 126 wherein
said radiofrequency ablation element is directional.

129. The system of claim 108 wherein
said energy delivery portion comprises an ultrasound ablation element.

10 130. The system of claim 129 wherein
said ultrasound ablation element is flexible.

131. The system of claim 129 wherein
15 said ultrasound ablation element is directional.

132. The system of claim 108 wherein
said energy delivery portion comprises an cryoablation element.

20 133. The system of claim 132 wherein
said cryoablation element is flexible.

134. The system of claim 132 wherein
25 said cryoablation element is directional.

135. The system of claim 108 wherein
said energy delivery portion comprises an fluid delivery element.

136. The system of claim 135 wherein
30 said fluid delivery element is flexible.

100522P-1241TESZ60

137. The system of claim 135 wherein
said fluid delivery element is directional.

138. The system of claim 108 wherein
5 said distal end portion of the flexible tubular member includes at least first and second sections, said first section having a loop configuration sized and dimensioned to substantially encircle an opening to a pulmonary vein, said second section extending from said first section and having a substantially longitudinal configuration.

10

139. The system of claim 138 wherein
said second section includes at least one electrode.

140. The system of claim 108 wherein
15 said distal end portion of the flexible tubular member is shaped to substantially encircle two or more pulmonary veins on an epicardial surface of the heart of the patient.

20

141. The system of claim 108 wherein
said ablative device comprises a microwave ablation element.

25

142. The system of claim 108 wherein
said flexible tubular member is sized and dimensioned to be transluminally positioned in an atrial chamber of the heart from a peripheral access vessel.

143. The system of claim 142 wherein
said peripheral access vessel is a femoral artery in a leg of the patient.

30

144. The system of claim 142 wherein
said peripheral access vessel is a femoral vein in a leg of the patient.

145. The system of claim 142 wherein
said peripheral access vessel is a radial artery or vein in an arm of the
patient.

5

146. The system of claim 142 wherein
said peripheral access vessel is a jugular artery or vein in a neck region
of the patient.

10 147. The system of claim 108 wherein
said flexible tubular member further comprises at least one electrode.

148. The system of claim 108 wherein
said ablative device comprises at least one electrode.

15 149. The system of claim 108 wherein
said distal end portion of the flexible tubular member includes at least
one temperature sensor for measuring a temperature of the tissue region during
ablation thereof.

20 150. The system of claim 108 wherein
said ablative device includes at least one temperature sensor which is
adapted to measure a temperature from within the flexible tubular member at
one or more locations along a length of the tubular member.

25 151. The system of claim 108 wherein
said distal end portion of the flexible tubular member includes at least
first and second sections, said first section having a loop configuration sized
and dimensioned to substantially encircle an opening to a pulmonary vein, said
30 second section extending distally from said first section and having a
substantially longitudinal configuration..

100-6217-2747-60

152. The system of claim 151 wherein

said second section includes at least one electrode

5 153. The system of claim 108 wherein

said flexible tubular member includes a key assembly to properly align the energy delivery portion within the distal end portion of the flexible tubular member such that the predetermined direction of the ablative energy aligns with the tissue region to be ablated.

10

154. The system of claim 141 wherein

said microwave ablation element comprises a microwave antenna which is located within an antenna assembly of the instrument for generating an electromagnetic field sufficient to cause ablation of said tissue region, said antenna assembly being adapted to direct the majority of the electromagnetic field generally in a predetermined direction across the distal end portion of the flexible tubular member.

15 155. The system of claim 154 wherein

20 said antenna is configured to generate said electromagnetic field substantially radially from a longitudinal axis of the antenna, and said antenna assembly includes an elongated shield extending partially around and generally in the direction of the longitudinal axis of the antenna, said shield defining an opening adapted to direct said majority of the electromagnetic field generally in said predetermined direction.

25 156. The system of claim 154 wherein

30 said flexible tubular member includes a key assembly to properly align the antenna assembly within the distal end portion of the flexible tubular member such that the predetermined direction of the electromagnetic field aligns with the tissue region to be ablated.

100-9212-00

157. The system of claim 123 wherein
said laser ablation element comprises a laser emitting element which is
located within a laser emitting assembly of the instrument for generating an
electromagnetic field sufficient to cause ablation of said tissue region, said laser
emitting assembly being adapted to direct the majority of the electromagnetic
field generally in a predetermined direction across the distal end portion of the
flexible tubular member.

158. The system of claim 157, wherein
said laser emitting element is configured to generate said
electromagnetic field substantially radially from a longitudinal axis of the laser
emitting element, and said laser emitting assembly includes an elongated
reflector extending partially around and generally in the direction of the
longitudinal axis of the laser emitting element, said shield defining an opening
adapted to direct said majority of the electromagnetic field generally in said
predetermined direction.

159. The system of claim 157 wherein
said flexible tubular member includes a key assembly to properly align the laser
emitting assembly within the distal end portion of the flexible tubular member
such that the predetermined direction of the electromagnetic field aligns with
the tissue region to be ablated.

160. The system of claim 132 wherein
said ultrasound ablation element comprises at least one ultrasound
transducer which is located within an ultrasound ablation assembly of the
instrument for generating an acoustic pressure wave sufficient to cause ablation
of said tissue region, said ultrasound ablation assembly being adapted to direct
the majority of the acoustic pressure wave generally in a predetermined
direction across the distal end portion of the flexible tubular member.

161. The system of claim 160, wherein
said ultrasound transducer is configured to generate said acoustic pressure wave substantially radially from a longitudinal axis of the ultrasound ablation element, and said ultrasound ablation assembly includes an good echogenic material extending partially around and generally in the direction of the longitudinal axis of the ultrasound transducer, said echogenic material defining an opening adapted to direct said majority of the acoustic pressure wave generally in said predetermined direction.

10

162. The system of claim 160 wherein
said flexible tubular member includes a key assembly to properly align the ultrasound ablation assembly within the distal end portion of the flexible tubular member such that the predetermined direction of the acoustic pressure wave aligns with the tissue region to be ablated.

15

163. The system of claim 132 wherein
said cryoablation element comprises a decompression chamber which is located within a cryoablation assembly of the instrument for generating a thermal sink sufficient to cause ablation of said tissue region, said cryoablation assembly being adapted to direct the majority of the thermal conduction generally in a predetermined direction across the distal end portion of the flexible tubular member.

20

25 164. The system of claim 163, wherein

said decompression chamber is configured to generate said thermal sink substantially radially from a longitudinal axis of the cryoablation element, and said cryoablation assembly includes an elongated thermal isolating element extending partially around and generally in the direction of the longitudinal axis of the cryoablation element, said thermal isolating element defining an

30

0002154760

opening adapted to direct said majority of the thermal conduction generally in said predetermined direction.

165. The system of claim 163, wherein

5 said flexible tubular member includes a key assembly to properly align the cryoablation assembly within the distal end portion of the flexible tubular member such that the predetermined direction of the majority of the thermal conduction aligns with the tissue region to be ablated.

10 166. The system of claim 108 wherein

 said flexible tubular member is substantially transparent to allow visualization of the ablative device within said tubular member.

167. The system of claim 120 wherein

15 said flexible tubular member is made from a material which has a low loss tangent.

168. The system of claim 108 wherein

 said flexible tubular member is made from a material which has a low water absorption coefficient.

169. The system of claim 123 wherein

 said flexible tubular member is made from a material which has a low scattering coefficient.

25 170. The system of claim 126 wherein

 said flexible tubular member is made from a material which has a electrical conductivity.

30 171. The system of claim 129 wherein

5 said flexible tubular member is made from a material working to provide a good mechanical impedance matching between the tissue and the ultrasound ablation element.

10 172. The system of claim 108, wherein
 said tubular member further includes a window portion in a portion of a side wall of the tubular member which extends longitudinally along at least a portion of the distal end portion of the tubular member.

15 173. The system of claim 172, wherein
 said energy delivery portion of the ablative device is configured to be exposed through the window portion of the tubular member for effecting ablation of tissue proximate to the window portion.

20 174. The system of claim 172, wherein
 said window portion is formed of a material used to obtain a good energy transfer between the ablative device and the tissue to ablate.

25 175. The system of claim 172, wherein
 said window portion is formed of a material with a low water absorption coefficient.

30 176. The system of claim 175, wherein
 said ablative device comprises at least one ultrasonic ablation element.

35 177. The system of claim 172, wherein
 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a ultrasonic ablation element.

40 178. The system of claim 172, wherein

100-121-2260
said window portion is formed of a laser transparent material and said ablative device comprises a laser emitting element.

179. The system of claim 172, wherein

5 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a laser ablation element.

180. The system of claim 172, wherein

10 said window portion is formed of a electrically conductive material and said ablative device comprises a RF ablation element.

181. The system of claim 172, wherein

15 said window portion is formed of a dielectric material having a low loss-tangent at microwave frequencies and said ablative device comprises a microwave ablation element.

182. The system of claim 172, wherein

20 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a microwave ablation element.

183. The system of claim 172, wherein

25 said window portion comprises a removed portion of the side wall of the tubular member and wherein said ablative device comprises a microwave ablation element.

184. The system of claim 122, wherein

30 said window portion is formed of a good thermal conductor material and said ablative device comprises a cryoablation element.

185. The system of claim 172, wherein
said window portion comprises a removed portion of the side wall of the
tubular member and wherein said ablative device comprises a cryoablation
element.

5

186. A system for ablating tissue within a body of a patient comprising:
an elongated flexible tubular member having at least one lumen and
including a malleable distal end portion which is shaped to be positioned
adjacent to or in contact with a selected tissue region within the body of the
10 patient; and

an ablative device which is configured to be slideably received
longitudinally within said at least one lumen and having an energy delivery
portion located near a distal end portion of said ablative device which is
adapted to be coupled to an ablative energy source.

15

187. The system of claim 186 wherein
said energy delivery portion and ablative energy source are working
together to produce the ablation of said selected tissue region.

20

188. The system of claim 189 wherein
said distal end portion of the flexible tubular member has a distal end
which is closed.

25

189. The system of claim 186 wherein
said energy delivery portion comprises a microwave ablation element.

190. The system of claim 189 wherein
said microwave ablation element is flexible.

30

191. The system of claim 189 wherein
said microwave ablation element is directional

100-222-111-111

192. The system of claim 186 wherein
said ablative device is a laser ablation element.

5 193. The system of claim 192 wherein
said laser ablation element is flexible.

194. The system of claim 192 wherein
said laser ablation element is directional.

10 195. The system of claim 186 wherein
said energy delivery portion comprises a radiofrequency ablation
element.

15 196. The system of claim 195 wherein
said radiofrequency ablation element is flexible.

197. The system of claim 195 wherein
said radiofrequency ablation element is directional.

20 198. The system of claim 186 wherein
said energy delivery portion comprises an ultrasound ablation element.

199. The system of claim 198 wherein
said ultrasound ablation element is flexible.

25 200. The system of claim 198 wherein
said ultrasound ablation element is directional.

30 201. The system of claim 186 wherein
said energy delivery portion comprises an cryoablation element.

006207-3247960

202. The system of claim 201 wherein
said cryoablation element is flexible.

5 203. The system of claim 201 wherein
said cryoablation element is directional.

204. The system of claim 86 wherein
said energy delivery portion comprises an fluid delivery element.

10 205. The system of claim 204 wherein
said fluid delivery element is flexible.

15 206. The system of claim 204 wherein
said fluid delivery element is directional.

207. A guide sheath comprising
a proximal end portion, a distal end portion, and at least one lumen
extending between the proximal and distal end portions, said at least one lumen
being sized and dimensioned to longitudinally slideably receive an ablative
device therethrough, said distal end portion having a preformed shape which is
moveable between a substantially linear configuration for insertion into and
through an introducer which is adapted to deliver the guide sheath into a
selected chamber within a heart of a patient, and an operable configuration
wherein said distal end portion has a loop shape configuration which is sized
and dimensioned to substantially encircle an opening to a pulmonary vein.

208. The guide sheath of claim 207 further including
a second section extending from said first section and having a
30 substantially longitudinal configuration.

0000000000

209. The guide sheath of claim 208 wherein
said distal end portion has a distal end which is closed.

210. The guide sheath of claim 208 wherein
5 said second section includes at least one electrode.

211. The guide sheath of claim 207 wherein
said guide sheath further includes a lumen used to inject a contrast
agent.

10

212. The guide sheath of claim 207 wherein
said loop shape configuration section includes at least one electrode.

213. The guide sheath of claim 208 wherein
15 said second section is configured to extend a short distance within the
opening to the pulmonary vein when said first section is located at or near the
tissue region extending about the periphery of the opening to the pulmonary
vein.

20 214. The guide sheath of claim 213 wherein
said electrode is configured to monitor electrical signals within the
pulmonary vein.

215. A guide sheath comprising
25 a proximal end portion, a distal end portion, and at least one lumen, the
distal end portion having a pre-shaped configuration including at least first and
second sections, said first section having a loop configuration sized and
dimensioned to substantially encircle an opening to a pulmonary, said second
section extending from said first section and having a substantially linear
30 configuration, said second section including at least one electrode.

00000000000000000000000000000000

216. A guide sheath comprising
a proximal end portion, a distal end portion, and at least one lumen
extending between the proximal and distal end portions, said at least one lumen
being sized and dimensioned to longitudinally slideably receive an ablative
device therethrough, said distal end portion having a preformed shape which is
moveable between a substantially linear configuration for insertion into and
through an introducer which is adapted to deliver the guide sheath into a
selected chamber within a heart of a patient, and an operable configuration
wherein said distal end portion has a curvilinear shape configuration which is
sized and dimensioned to substantially follow the wall of a interior cardiac
chamber.

217. The guide sheath of claim 216 wherein
said interior cardiac chamber is selected from a right or a left atrium.

218. The guide sheath of claim 216 wherein
said interior cardiac chamber is selected from a right or a left ventricle.

219. The guide sheath of claim 216 wherein
said distal end portion includes at least one electrode.

220. The guide sheath of claim 216 wherein
said curvilinear shape is configured to substantially follow the posterior
wall of the left atrium between two pulmonary veins.

221. The guide sheath of claim 216 wherein
said curvilinear shape is configured to substantially follow the posterior
wall of the left atrium between a pulmonary vein and the mitral valve.

222. The guide sheath of claim 216 wherein

said curvilinear shape is configured to substantially follow the posterior wall of the left atrium between a pulmonary vein and the left atrial appendage.

223. The guide sheath of claim 216 wherein

5 said curvilinear shape is configured to substantially follow the isthmus between the inferior caval vein and the tricuspid valve.

224. The guide sheath of claim 216 wherein

10 said curvilinear shape is configured to substantially follow the lateral right free wall between the superior and inferior caval veins.

225. A method of conducting a surgical ablation procedure on a heart of a patient comprising:

15 providing an ablation sheath comprising a proximal end portion a distal end portion and at least one lumen;

providing an ablative device which is configured to be longitudinally received within said at least one lumen of said ablation sheath, said ablative device having an energy delivery portion which is adapted to be coupled to a source of ablative energy;.

20 making at least one incision in a patient's chest to access the heart;

introducing the ablation sheath through said incision and positioning the distal end portion of the sheath adjacent to or in contact with a tissue surface of the heart;

25 advancing said ablative device through the ablation sheath such that the energy delivery portion of the device is located at least partially within said distal end portion of the sheath; and

forming at least one lesion along the tissue surface of the heart by applying energy to said energy delivery portion to effect ablation of tissue.

30 226. The method of claim 225 wherein

 said distal end portion is pre-shaped.

000000-000000-000000

227. The method of claim 225 wherein
said distal end portion is malleable.

5 228. The method of claim 225 wherein
said distal end portion is flexible.

229. The method of claim 225 further comprising
forming at least one penetration in a wall of the heart into an interior
10 chamber thereof and introducing the ablation sheath through the penetration to
perform an ablative procedure within the internal chamber of the heart.

15 230. The method of claim 229 wherein
the internal chamber is selected from the right atrium or left atrium.

231. The method of claim 229 wherein
the internal chamber is selected from the right ventricle or left ventricle.

20 232. The method of claim 229 wherein
said forming at least one penetration in a wall of the heart is performed
using a cutting member on a distal end of the ablation sheath.

25 233. The method of claim 225 wherein
the heart remains beating during the ablation procedure.

234. The method of claim 225 further comprising
arresting the patient's heart prior to said forming at least one lesion.

30 235. The method of claim 225 wherein
said incision is a median or partial sternotomy incision.

236. The method of claim 225 wherein
said incision is a minimal thoracotomy.

5 237. The method of claim 225 wherein
the size of said incision is not substantially greater than about 12 cm.

238. The method of claim 225 wherein
the formation of said at least one lesion is visualized by a thoracoscope.

10 239. The method of claim 225 further comprising
performing at least one portion of a coronary artery bypass graft
procedure prior to or after said formation of at least one lesion.

240. The method of claim 225 further comprising
repeating said forming at least one lesion at least one or more times to
form two or more overlapping lesions on the heart.

15 241. The method of claim 225 wherein
said distal end portion of the sheath is positioned adjacent to or in
contact with at least a portion of the transverse sinus preparatory to treating
atrial fibrillation.

20 242. The method of claim 225 wherein
said distal end portion of the sheath is positioned adjacent to or in
contact with at least a portion of the oblique sinus preparatory to treating atrial
fibrillation.

25 243. The method of claim 225 wherein
said distal end portion of the sheath is positioned adjacent to or in
contact with at least a portion of the tissue connecting a pulmonary vein to the
left appendage.

006207-022600

244. The method of claim 225 wherein
said positioning the distal end portion of the sheath comprises
puncturing at least one portion of the pericardial reflexion.

5

245. The method of claim 244 wherein
said portion of the pericardial reflexion is located around a pulmonary
vein.

10 246. The method of claim 240 wherein
at least a portion of respective ones of said plurality of lesions overlap
one another to form a continuous lesion.

247. The method of claim 246 wherein
15 said plurality of lesions are formed in a substantially rectilinear pattern.

248. The method of claim 246 wherein
said plurality of lesions are formed in a substantially curvilinear pattern.

20 249. The method of claim 246 wherein
said plurality of lesions are formed in a substantially annular pattern.

250. The method of claim 225 wherein
25 said ablative device comprises a microwave ablation element.

251. The method of claim 225 wherein
said ablative device comprises a radiofrequency ablation element.

252. The method of claim 225 wherein
30 said ablative device comprises an ultrasound element.

00000000000000000000000000000000

253. The method of claim 225 wherein
said ablative device comprises a laser emitting element.

254. The method of claim 225 wherein
5 said ablative device comprises a fluid delivery probe.

255. The method of claim 225 wherein
said ablative device comprises a cryogenic element.

10 256. A system for ablating tissue within a body of a patient comprising:
an elongated rail device adapted to be positioned proximate and adjacent
to a selected tissue region to be ablated within the body of the patient; and
an ablative device having a receiving passage configured to slideably
receive said rail device longitudinally therethrough to slideably position the
15 ablative device substantially adjacent to or in contact with the selected tissue
region, said ablative device having an energy delivery portion which is adapted
to be coupled to an ablative energy source.

20 257. The system of claim 256 wherein
said ablative device and ablative energy source are working together to
produce the ablation of said selected tissue region.

258. The system of claim 256 wherein
said ablative energy source is a microwave generator and said ablative
device includes a microwave ablation element.

259. The system of claim 256 wherein
said ablative energy source is a radiofrequency generator and said
ablative device includes a radiofrequency ablation element.

30 260. The system of claim 256 wherein

006200-2021072620
said ablative energy source is a ultrasound generator and said ablative device includes a ultrasound ablation element.

261. The system of claim 256 wherein
5 said ablative energy source is a laser generator and said ablative device includes a laser ablation element.

262. The system of claim 256 wherein
10 said ablative energy source includes a compressor and a compressible gas, and said ablative device includes a cryoablation element.

263. The system of claim 256, wherein
15 said rail device includes a pre-shaped distal portion.

264. The system of claim 256, wherein
20 said rail device includes a malleable distal portion

265. The system of claim 256, wherein
25 said ablative device is flexible.

266. The system of claim 256, wherein
30 said ablative device is adapted to directionally emit the ablative energy from the energy delivery portion.

267. The system of claim 266 further including:
a key assembly cooperating between the ablative device and the rail member to properly align the directionally emitted ablative energy toward the tissue region to be ablated.

268. The system of claim 267, wherein

the rail device includes a non-circular transverse cross-sectional dimension, and the receiving passage of the ablative device includes a substantially similarly shaped non-circular transverse cross-sectional dimension to enable sliding of the ablative device in a manner continuously aligning the directionally emitted ablative energy toward the tissue region to be ablated as the ablative device advances along the rail device.

5

269. The system of claim 268, wherein
the transverse cross-sectional dimensions of the rail device and the
10 receiving passage are rectangular-shaped.

15

270. The system of claim 268, wherein
the transverse cross-sectional dimensions of the rail device and the
receiving passage are oval-shaped.

20

271. The system of claim 267, wherein
one of the rail device and an interior wall, defining receiving passage of
the ablative device, includes a key notch, and the other of the interior wall and
the rail device defines a matching keyway to continuously align the
directionally emitted ablative energy toward the tissue region to be ablated as
the ablative device advances along the rail device.

25

272. The system of claim 267 wherein
said energy delivery portion is provided by a microwave ablation
element.

30

273. The system of claim 272 wherein
said microwave ablation element comprises a microwave antenna which
is located within an antenna assembly of the ablative device for generating an
electromagnetic field sufficient to cause ablation of said tissue region, said
antenna assembly being adapted to direct the majority of the electromagnetic

field generally in a predetermined direction across the distal end portion of the flexible tubular member.

274. The system of claim 273 wherein

5 said antenna is configured to generate said electromagnetic field substantially radially from a longitudinal axis of the antenna, and said antenna assembly includes an elongated shield extending partially around and generally in the direction of the longitudinal axis of the antenna, said shield defining an opening adapted to direct said majority of the electromagnetic field generally in
10 said predetermined direction.

275. A method of ablating tissue within a body of a patient comprising:

 providing an elongated rail device having a distal portion;

15 providing an ablative device having a receiving passage configured to slideably receive said rail device longitudinally therethrough, said ablative device having an energy delivery portion which is adapted to be coupled to an ablative energy source;

20 introducing said rail device into the patient's body and positioning the distal portion thereof proximate and adjacent to a selected tissue region to be ablated;

 slideably positioning the ablative device along the rail until the energy delivery portion is located substantially adjacent to or in contact with the selected tissue region; and

25 delivering ablative energy to said energy delivery portion to ablate said tissue region.

276. The method of claim 275 wherein

 the distal end portion is pre-shaped.

30 277. The method of claim 275 wherein
 the distal end portion is malleable.

278. The method of claim 275 wherein
said introducing said rail device into the patient's body comprises
introducing the rail device through an opening in the body of the patient.

5 279. The method of claim 275 further comprising
repositioning the energy delivery portion of the ablative device along the
distal end portion of the rail device at least once to form a plurality of
strategically positioned lesions along said tissue region.

10 280. The method of claim 279 wherein
at least a portion of respective ones of said plurality of lesions overlap
one another to form a continuous lesion.

15 281. The method of claim 275, wherein
said ablative device is adapted to directionally emit the ablative energy
from the energy delivery portion; further including:
aligning the directionally emitted ablative energy toward the tissue region to be
ablated through a key assembly cooperating between the ablative device and
the rail member to properly.